

Exhibit L

1
2 IN THE UNITED STATES DISTRICT COURT
3 FOR THE SOUTHERN DISTRICT OF NEW YORK
4

5 UMB BANK, N.A., as Trustee,)
6)
7 Plaintiff,) No. 1:15-CV-08725
8) (GBD) (RWL)
9 vs.)
10)
11 SANOFI,)
12)
13 Defendant.)
14 -----)
15

16 VIDEOTAPED DEPOSITION OF JANICE A. PHILLIPS
17 New York, New York
18 Thursday, March 21, 2019
19
20
21

22
23 Reported by:
24 KRISTIN KOCH, RPR, RMR, CRR
25 JOB NO. 156495

1 J. Phillips

2 these reports that you had a complete and
3 thorough understanding of the operations that
4 allowed you to provide the findings in your
5 report?

6 A. I would represent that what I had
7 written in the report was based on the
8 information that I had received during the due
9 diligence.

10 Q. Okay. And that's a caveat of some
11 sort, right, because you don't have access to
12 perfect information in due diligence; right?

13 A. Correct.

14 Q. Okay. Now, I know that you speak
15 about potential supply shortages in paragraphs
16 59 to 61 of your report, which we will get to a
17 little later, but were there any other points
18 in your career when you faced a supply shortage
19 for a product?

20 A. No.

21 Q. Okay. At any point in your career
22 were you responsible for a -- the manufacturing
23 of a product at a facility that was subject to
24 an ongoing FDA Consent Decree?

25 A. No.

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2 Now, you also say that the supply
3 issues were markedly improved in 2012 as a
4 result of these initiatives; right?

5 A. I'm not sure that I said that. I
6 think that they said that.

7 Q. Well, I am just saying that you say
8 it in your report.

9 A. Correct.

10 Q. Okay. By how much?

11 A. They never indicated in any of their
12 documents. It was a qualitative statement.

13 Q. Okay. So you didn't independently
14 measure them, did you?

15 A. I made some attempt when the
16 information was available in order to be able
17 to determine that.

18 Q. But did you actually reach a
19 conclusion as to quantitatively how much it
20 improved?

21 A. No, I didn't, because I didn't have
22 the data available to me to do that.

23 Q. Okay. So how can you state at the
24 beginning of this paragraph that had Sanofi
25 taken initiative as early as possible, the

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2 Production Milestone would have been met?

3 A. This is a simple movement of the
4 timeline. They took initiatives in the --
5 no -- no earlier than the beginning of the
6 third quarter of 2011, okay, and they started
7 to see improvement in the latter portion of
8 2011 that resulted in essentially achievement
9 of their Production Milestones in first quarter
10 of 2012. If you had moved that all back at
11 least one quarter and possibly a little bit
12 more than that, you could have achieved those
13 Production Milestones within 2011.

14 Q. You just said you didn't quant --
15 you didn't quantify the improvement in 2012, so
16 how do you know that the Production Milestones
17 were met in 2012?

18 A. I believe that I referenced a
19 document that said that they had met the
20 production targets by simply tallying up the
21 vial equivalents of Cerezyme and Fabrazyme that
22 they had produced by the end of the third --
23 first quarter of 2012. So if I misspoke by
24 saying I didn't do a quantitative analysis, I
25 did have access to Fabrazyme and Cerezyme Excel

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2 MR. GILMAN: Objection.

3 A. So I would have to go back to my --
4 I would have to go back through my notes, okay,
5 and check the exact -- where I was pinpointing
6 the exact timeline, because -- so let's -- so
7 no actions actually occurred of any substance
8 until Bill Aitchison arrived on site at
9 Genzyme. His actions seemed to have been
10 started, and I say "seemed to," because this is
11 a deduction from the documents, seemed to --
12 after he received an initial -- he received his
13 initial updates from Genzyme personnel, seemed
14 to have been started in the August, September
15 time frame. Four months backwards from
16 September would have moved some of those
17 actions, specifically the quality -- the
18 attention to the deviation closure, okay, would
19 have moved some of that back to a time frame
20 that would have been after the closure of the
21 merger.

22 Q. Okay. Is it your opinion that if
23 these actions started on April 1st, 2011, that
24 the Production Milestone would have been met?

25 A. Yes.

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2 Q. What is your basis for that?

3 A. It's the analysis of the data that I
4 had on vial equivalents that were released over
5 the period of time from the beginning of
6 January 2011 through the third -- first quarter
7 of 2012.

8 Q. But that assumes that Bill Aitchison
9 would have been initiating all of these actions
10 on April 1st; correct?

11 MR. GILMAN: Objection.

12 A. The -- so -- so the effect of the --
13 so Bill -- Bill Aitchison started a series of
14 conversations and activities that resulted in a
15 set of actions that appeared to have been --
16 started to take place around the September time
17 frame, okay, that were already starting to
18 have, from the documentation, already starting
19 to have impact by the end of 2011. If Bill
20 Aitchison had started his conversations back in
21 April, those same actions would have
22 occurred -- might -- might have had impact --
23 would have had impact four -- four months
24 earlier. Now, meeting the CVR was not just --
25 not just the issue of the clearly identifiable

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2 through that process; right?

3 A. That's correct.

4 Q. Okay. Did you analyze what the
5 process would look like for each of these
6 changes?

7 A. I did not -- I did not do that
8 detailed analysis of -- because, as I said, all
9 right, I was dealing with the technical aspects
10 of the process, okay, and not the other aspects
11 of any one of these activities that would
12 relate to regulatory issues.

13 Q. Okay. So how can you claim that
14 these would be -- how can you claim that these
15 would result in an increase in vial equivalent
16 releases by December 31st, 2011, if you haven't
17 conducted that analysis?

18 A. From a technical perspective, these
19 would have ended up producing a number -- if
20 they could have been implemented in a
21 satisfactory time frame, these would have
22 resulted in that increase in vials.

23 Q. But that's an assumption, isn't it,
24 if they could have been implemented in a
25 satisfactory time frame?

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2 A. But I am asked only for a technical
3 opinion.

4 Q. Okay. But you need that assumption
5 in order to reach the conclusion that they
6 would have had a beneficial impact on releases
7 by December 31st, 2011, don't you?

8 A. You need the detailed analysis that
9 considers all of the aspects of what it takes
10 to finish any of these activities.

11 Q. That wasn't my question.

12 My question is don't you need to
13 know how long a regulatory filing would take to
14 receive approval in order to reach the
15 conclusion that these would have a beneficial
16 impact on releases by December 31st, 2011?

17 A. Ultimately whether or not they could
18 be implemented would be a consideration, and
19 yes, I would say yes.

20 Q. Okay. But, again, it doesn't really
21 matter whether these were implemented by
22 December 31st. What matters is whether their
23 implementation would have resulted in releases
24 by December 31st; correct?

25 A. Correct.

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2 A. -- for Cerezyme and Fabrazyme.

3 Q. Right. But as we discussed before,
4 when there is a low probability of achieving
5 the proposed project within the relevant time
6 period, it becomes something that you would
7 potentially scrap from that project; correct?

8 A. If at the time at which the plan --
9 the strategic analysis discussion occurred and
10 this project was brought forward and this type
11 of timeline was put forth, right, and fully
12 vetted to assure that it was as aggressive a
13 timeline as they possibly could achieve, all
14 right, then yes, this would -- I would give
15 this a lower probability of success.

16 Q. So you are not claiming that Sanofi
17 could have done this, much less released
18 product using this change by December 31st,
19 2011, you are just saying that it failed to
20 consider it?

21 A. Correct. Consider it and consider
22 whether or not this is the most aggressive
23 strategy, the appropriate and most aggressive
24 strategy that they could have taken.

25 Q. Okay. In the next bullet down you

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2 Q. So how can you claim that making
3 this change back to Fitz mill would have met
4 the Production Milestone or even increased the
5 amount of releases by December 31st, 2011?

6 A. I want to go back to my previous
7 point, okay, and that is that this would have
8 been one of the aspects of what the Genzyme
9 organization understood as potentially
10 impacting their process that they would have
11 taken under consideration if they were looking
12 at ways in which they could have addressed the
13 Production Milestone.

14 Q. Okay. And just to make sure we are
15 on the same page here, all of these things that
16 you list in all of these bullets in paragraph
17 83 are things that should have been considered,
18 not necessarily things that would have resulted
19 in releases in 2011, not necessarily things
20 that would have met the Production Milestone;
21 right?

22 A. Not -- not necessarily, because as
23 we pointed out, okay, some of these may have
24 required regulatory filings that would have
25 extended past 2011.

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2 A. And these are potential lots that
3 could -- for which that could be done.

4 Q. And so you are just simply offering
5 the opinion that it was something that was
6 possible, not something that could have been
7 achieved?

8 MR. GILMAN: Objection.

9 A. I think the statement says
10 "formulated bulk material suitable for fill and
11 finish in 2011," and it was suitable for fill
12 and finish in 2011, would have accounted for an
13 additional 42,890 vial equivalents, and if that
14 had been able to go through fill and finish in
15 2011, that's the vial equivalents. So it was
16 suitable -- I -- I was very careful with the
17 wording, okay, it was suitable for fill and
18 finish.

19 Q. I have no doubt that you were
20 careful with the wording.

21 What I am asking is whether you have
22 reached a definitive conclusion that it would
23 have counted towards the milestone if Sanofi
24 used commercially reasonable efforts, or if it
25 was simply a possibility and you did not

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2 analyze it further?

3 A. It was one of the issues that Sanofi
4 needed -- Sanofi Genzyme needed to take under
5 consideration in exercising commercially
6 reasonable efforts to meet the milestone in a
7 timely fashion.

8 Q. And because you don't know the
9 complexities of the pooling strategy, you have
10 no way of determining --

11 A. I cannot --

12 Q. -- whether it was even possible?

13 A. I cannot determine it definitively.

14 Q. Okay. And the same would go for any
15 of the other assertions in these bullets about
16 vials filled/finished in March 2012; correct?

17 MR. GILMAN: Objection.

18 A. Could you reask that -- could you
19 reask me that question.

20 Q. The same is true for all of these
21 bullets, basically?

22 MR. GILMAN: Objection.

23 A. So the suggestion that these could
24 have -- each one of these, each one of these
25 bullets could have been used to satisfy the CVR